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<b>Notice of Allowability</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/026,415		KAYLOR ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Lyle A. Alexander		1743	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the 1/4/07 Interview Summary.
2. ☒ The allowed claim(s) is/are 51,54-55, 57-63,65-72 renumbered as 1-18 respectively.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
  - \* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| <ol style="list-style-type: none"> <li>1. <input type="checkbox"/> Notice of References Cited (PTO-892)</li> <li>2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br/>Paper No./Mail Date _____</li> <li>4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br/>of Biological Material</li> </ol> | <ol style="list-style-type: none"> <li>5. <input type="checkbox"/> Notice of Informal Patent Application</li> <li>6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br/>Paper No./Mail Date <u>1/4/07</u>.</li> <li>7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment</li> <li>8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance</li> <li>9. <input type="checkbox"/> Other _____.</li> </ol> |
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An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Klosowski on 1/8/07.

See the attached claims titled "FOR EXAMINER'S AMENDMENT".

The following is an examiner's statement of reasons for allowance: In addition to the remarks of record, the cited prior art fails to teach or suggest the claimed device with a fluidic guide having a first end where the sample and electromagnetic radiation are applied and a second end in direct fluid communication with a wicking agent that communicates the sample with a binder that will produce a diffraction pattern indicative of the analyte of interest.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lyle A Alexander  
Primary Examiner  
Art Unit 1743

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Kaylor, et al.	)	Examiner: Alexander, Lyle
	)	
Serial No.: 10/026,415	)	Art Unit: 1743
	)	
Filed: December 21, 2001	)	Deposit Acct. No.: 04-1403
	)	
Title: Diagnostic Device, System and Method	)	Confirmation No.: 2521
	)	

**FOR EXAMINER'S AMENDMENT**

1-50. (Cancelled).

51. (Currently Amended) A diffraction-based assay device for detecting the presence of an analyte, the device comprising:

a substrate that comprises a polymer film, wherein a first binder is present on the substrate in a pattern;

a fluidic guide ~~that is~~ with a first end and a second end in direct communication with ~~the substrate~~ a wicking agent, wherein the first end of the fluidic guide defines an opening therein for sample application and includes at least one channel through which a fluid test sample is capable of flowing via capillary action to the second end,~~[[;]]~~

~~[[a]]~~ wherein the wicking agent ~~that~~ is capable of receiving the fluid test sample from the second end of the fluidic guide and thereafter facilitating contact of the fluid sample with the binder on the substrate; and

an electromagnetic radiation source that is configured to direct electromagnetic radiation to the substrate through the first end of the fluidic guide to the opening for generating to generate a diffraction pattern proximate an area of the substrate defined by the ~~opening~~ second end of the guide.

52-53. (Cancelled)

54. (Previously Presented) The diffraction-based device of claim 51, wherein the wicking agent defines an opening through which the electromagnetic radiation is capable of passing.

55. (Previously Presented) The diffraction-based device of claim 51, wherein a second binder is also present on the substrate.

56. (Cancelled)

57. (Currently Amended) The diffraction-based device of claim ~~56~~ 51, wherein the first opening is beveled.

58. (Previously Presented) The diffraction-based device of claim 51, wherein the fluidic guide is generally linear.

59. (Previously Presented) The diffraction-based device of claim 51, wherein the fluidic guide has one or more turns or branches.

60. (Previously Presented) The diffraction-based device of claim 51, wherein the fluidic guide is positioned generally perpendicular to the substrate.

61. (Previously Presented) The diffraction-based device of claim 51, wherein the fluidic guide is in communication with a well, the well initially receiving the fluid sample.

62. (Currently Amended) The diffraction-based device of claim 51, wherein the fluidic guide is positioned directly adjacent to and in fluid communication with the wicking agent.

63. (Previously Presented) The diffraction-based device of claim 51, wherein the substrate comprises the metal coating.

64. (Cancelled)

65. (Previously Presented) The diffraction-based device of claim 51, further comprising a detector for detecting the diffraction pattern.

66. (Previously Presented) The diffraction-based device of claim 51, wherein the diffraction pattern is generated only upon exposure of the substrate to the analyte.

67. (Previously Presented) The diffraction-based device of claim 51, wherein the polymer film is generally transparent to the electromagnetic radiation.

68. (Currently Amended) A diffraction-based assay device for detecting the presence of an analyte, the device comprising:

a substrate that comprises a polymer film, wherein a first binder is present on the substrate in a pattern;

a fluidic guide ~~that is~~ with a first end and a second end in direct communication with ~~the substrate~~ a wicking agent, wherein the first end of the fluidic guide defines an opening therein for sample application and includes at least one channel through which a fluid test sample is capable of flowing via capillary action to the second end;

means for venting pressure to facilitate movement of the fluid test sample in a direction of the substrate;

[[a]] wherein the wicking agent ~~that is~~ capable of receiving the fluid test sample from the second end of the fluidic guide and thereafter facilitating contact of the fluid sample with the binder on the substrate; and

an electromagnetic radiation source that is configured to direct electromagnetic radiation to the substrate through the ~~opening for generating~~ the first end of the fluidic guide to generate a diffraction pattern proximate an area of the substrate defined by the ~~opening~~ second end of the guide.

69. (Previously Presented) The diffraction based device of Claim 68, wherein the means for venting pressure is a pressure vent disposed proximate the wicking agent in communication with the wicking agent and external atmosphere.

70. (New) The diffraction-based device of claim 68, wherein the substrate further comprises a metal coating.

71. (New) The diffraction-based device of claim 51, wherein the substrate further comprises a metal coating.

72. (Currently Amended) A diffraction-based assay device for detecting the presence of an analyte, the device comprising:

a substrate that comprises a polymer film, wherein a binder is present on the substrate in a pattern;

a fluidic guide with a first and second end that is in direct communication with the ~~substrate~~ wicking agent, wherein the first end of the fluidic guide receives a fluid test sample and includes at least one channel through which ~~[[a]]~~ the fluid test sample is capable of flowing via capillary action to the second end, ~~[[;]]~~

~~[[a]]~~ the wicking agent defining a hole therethrough and capable of receiving the fluid test sample from the second end of the fluidic guide and thereafter facilitating contact of the fluid sample with the binder on the substrate; and

an electromagnetic radiation source that is configured to direct electromagnetic radiation to the substrate through the ~~hole for generating~~ first end of the fluidic guide to generate a diffraction pattern proximate an area of the substrate defined by the ~~hole~~ second end of the guide.